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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,422	01/30/2002	Hyeyoung Lee	0217-0008	4749

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

18

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/058,422

Applicant(s)

Seoul et al.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 23, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10, 13, and 14 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 and 5 6) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Claims 1-7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group I, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 12.

2. Applicant's election with traverse of Group II, claims 8-14 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that both groups in the same application would not constitute an undue burden to search and examine together. This is not found persuasive because group II, claims 8-14 are drawn to recombinant oligonucleotides, probes and the kit containing the oligonucleotides and the probes in which the oligonucleotides and probes can be used in nucleic acid purification. Thus, the Applicant's arguments filed 5/23/2003 have been fully considered but they are not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Now claims 8-14 are examined with SEQ ID NO: 1-3, 5-6, 9-10 and 13-14 as follows.

Claim Objections

3. Claims 10-14 are objected to because of the following informalities: claims 10-14 have some of the nucleic acids which are elected and it is suggested to amend the claims to contain the elected nucleic acid sequences only. Appropriate correction is required.

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Sequence Rules

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth as follows:

All nucleic acid sequences in the specification are required to have sequence identification number, for example, the nucleic acid sequence in fig. 2.

APPLICANT IS GIVEN THE RESPONSE PERIOD SET FORTH IN THIS OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a. Claim 11 is vague and indefinite because the phrase "the wild type *M. tuberculosis rpoB* gene" has no antecedent basis.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 10 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al. (WO 01/31061).

Lee et al. disclose oligonucleotide probe, "PAN-MYC" which has the same nucleic acid sequence as SEQ ID NO: 3 (See pg. 15, table 2). The oligonucleotide probe is designed for Mycobacterial species identification (See pg. 15, lines 28-29). Thus the teachings of Lee et al. anticipate the limitations of claims 10 and 13.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 8-9, and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (WO 01/31061).

Lee et al. disclose a method of identification of *Mycobacterium* strain via PCR. The *Mycobacteria* strain is identified by the method as follows: *M. tuberculosis* (See pg. 3, lines 9-13). The primer(RPO5') is used to amplify the region of the *rpoB* (See pg. 13, lines 5-7). The primer (RPO5') has the same sequence as the nucleic acid sequence SEQ ID NO: 1 except that the nucleic acid sequence SEQ ID NO: 1 has additional -CCTGGC- at its 3' end.

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the primer of Lee et al. (WO 01/31061) to amplify a 531 bp fragment of the *rpoB* gene for identifying *Mycobacterium tuberculosis* and MOTT and construct the kit to contain the primer of Lee et al. (WO 01/31061) because Lee et al. disclose that the amplified regions are highly polymorphic regions and are highly species-specific, and therefore, it is very

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useful to design mycobacterial species-specific oligonucleotide probes for the identification (See pg. 21, lines 2-10). Thus, it would have been prima facie obvious to construct nucleic acid SEQ ID NO: 1 and the kit containing the nucleic acid sequence for identifying *Mycobacterium tuberculosis* and MOTT.

Summary

11. No claims are allowable.
12. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

J.T.
August 5, 2003


ETHAN WHISENANT
PRIMARY EXAMINER